DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

M3418A

January 10, 2000

WARNING LETTER
CHI-9-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David McConkey
Chief Executive Officer
Good Samaritan Hospital
3815 Highland Avenue
Downers Grove, IL 60515

Dear Mr. McConkey:

During a Food and Drug Administration (FDA) inspection of your hospital blood bank on November 15 & 16, 1999, Investigator Jeanne Morris documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 606 as follows:

> Failure to conduct a thorough investigation following an adverse reaction that arose as a result of blood collection or transfusion [21 CFR 606.170(a)]. The inspection revealed that on November 9, 1999, incompatible blood was issued to patient [redacted]. Our inspection found that as of November 16, 1999, there was no documentation of any interview with the technologist that performed the original crossmatch on November 8, 1999. Because of the failure to document an interview with the technologist, no information was available concerning any other tests the technologist was performing simultaneously in the testing rack, identification of equipment used to perform the assay, the assay method used by the technologist or other factors which may have been related to the incident.
>
> The investigation also failed to include the retest all of the other samples that were tested by the technologist at the time of the crossmatch. No retests were performed on units [redacted] and [redacted]
>
> Failure to maintain and follow adequate written standard operating procedures (21 CFR 606.100 (b)]. For example, the inspection revealed that operating procedures for this blood bank requires the use of the MTS Gels procedure for antibody screen test. The inspection revealed that the technician did not use this test, but instead used a test tube method. It was also revealed that in an internal memorandum issued 7/27/99, that effective 8/2/99, all antibody screens, antibody panels and Coombs crossmatches are to be done by the gel test method.

However, the SOPs covering this procedure were not updated to reflect this policy change at the time of the conclusion of the inspection.

Failure to maintain equipment quality control [21 CFR 606.60(a)]. For example, the centrifuge, dispenser and the ID-Pipetor FP-2 used with the [redacted] system was not calibrated upon receipt or at any time after installation. In addition, test performance verification assessment was not fully documented.

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of federal regulations, with regard to blood collection, processing, testing and distribution. You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

At the conclusion of the inspection, a Form FDA- 483, List of Inspectional Observations (FDA-483), was issued to and discussed with Dr. William D. Dwyer, Chairman of the Department of Pathology. A copy is attached for your information.

We have received a written response to the FDA-483, dated December 23, 1999, from Dr. Dwyer. Dr. Dwyer indicates that several written operating procedures have been revised and equipment used in the blood banking operation have been calibrated. However, in some instances, the response to specific items listed in the FDA-483 require additional clarification as follows:

FDA 483 items #1& 2. During the inspection, no documentation of an interview with the technologist was available. Dr. Dwyer, states that the technologist was interviewed on November 18, 1999, and a second time on December 1, 1999. Please provide us with a copy of the interviews. We also would like a copy of the results of your investigation, and please furnish a copy of the medical examiner's report.

FDA 483 item #3. Dr. Dwyer stated that the technologist followed current written procedures that require that patient's antibodies be identified at six-month intervals. He stated in his response that if FDA has literature to support a different frequency for performing Antibody ID for known positive Antibody Screens, he would welcome our comments. During the inspection, Investigator Morris was told that the six-month interval for antibody identification listed in the SOP, was taken from recommendations contained in the AABB Technical Manual.

FDA has not issued any guidance documents pertaining to this issue. On issues in which FDA has not issued a policy guideline, we usually cite AABB's recommendations or routine industry practice. AABB, in the 19th edition of its Standards manual, section 1400, TESTING OF RECIPIENT BLOOD, pages 58 & 59, addresses this issue. Section 14.020 states "If the patient has been transfused in the preceding 3 months with blood or a blood component containing allogeneic red cells, has been pregnant within the preceding 3 months, or if the history is uncertain or unavailable, a sample shall be obtained from the patient within 3 days of the scheduled transfusion. Day 0 is the day of draw." Also, section 14.310 directs "In patients with previously identified clinically significant antibodies, antibody identification shall be performed when there is clinical or serologic evidence of a new antibody."

Given the history of multiple prior transfusions for patient [redacted], we believe that identification should have been conducted on this patient's antibodies following the positive antibody screen assay. We can find no recommendation for a six-month interval in Antibody ID in either AABB's Technical Manual or Standards.

FDA-483 item #5a. Please furnish the results of the calibration(s).

FDA-483 item #8. When do you expect to complete the validation? Please provide this office with the results of the study.

Please notify this office in writing within 15 working days of receipt of this letter regarding the specific steps you have taken to correct the above violations, including an explanation of each being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed. You may reference corrective actions discussed in Dr. Dwyer's December 10, 1999 letter, where applicable.

Your response should be sent to the attention of George F. Bailey, Compliance Officer.

Sincerely,

\s\
Raymond V. Mlecko
District Director